

CHR Renewal--Tobacco Exposure and Semen Biomarkers

1. STATUS REPORT

Initial human subject approval date for the study was July 19, 1990 and it expires July 15, 1991. During this first year [REDACTED] participants have been recruited to the study and [REDACTED] have refused to participate. The number estimated to complete the study is approximately [REDACTED]. To date the principal items collected have been the field samples of saliva and semen, complete questionnaires, and the brief smoking questionnaire. Saliva and semen samples were processed in the field, frozen and are currently in storage at SFGH.

There have been no changes in anticipated risks or benefits. There have been no unanticipated side effects noted during the first year of the study. There have been no modifications to the original protocol.

2. PLANS FOR THE COMING YEAR

Subject recruitment will continue into the first two months of this academic year through the end of September. The goal will be to recruit a total of [REDACTED] subjects. After all saliva and semen samples have been collected, the laboratory processing will begin. This will involve, as stated in the original protocol, a gas chromatography and mass spectroscopy of the saliva and semen samples for cotinine and nicotine. After the laboratory analysis is completed, data entry will begin and the statistical analysis will begin. It is possible that the study protocol may be modified to extend into a third year depending on the length of time involved with data entry and data analysis.

4. APPROVED PROTOCOL

There have been no changes to the previously approved protocol.

5. CONSENT DOCUMENTS

The original and approved consent documents are attached.

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